DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

July 2, 2015

3M Health Care
Matt Mortensen, PhD, RAC
Regulatory Affairs Lead
3M Center
Building 275-5W-06
St. Paul, MN 55144

Re: K150477
Trade/Device Name: 3M Comply™ 1224 Indicator Tape for Ethylene Oxide (EO) Sterilization
Regulation Number: 21 CFR 880.2800
Regulation Name: Physical/chemical sterilization process indicator
Regulatory Class: II
Product Code: JOJ
Dated: June 4, 2015
Received: June 5, 2015

Dear Dr. Mortensen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150477

Device Name
3M Comply 1224 Indicator Tape for Ethylene Oxide (EO) Sterilization

Indications for Use *(Describe)*
The tape is designed to secure packs wrapped with untreated woven (i.e., reusable 100% cotton and cotton/poly blends) and disposable non-woven, paper, paper/plastic, and spunbond polyolefin/plastic wraps.

United States
Use the EO indicator tape to demonstrate that packs have been exposed to one of the EO sterilization processes in the table below and to distinguish between processed and unprocessed packs.

EO Gas Concentration	Exposure Time	Temperature	Relative Humidity %
736 mg/ L	4.5 hours	38°C	40 – 80 %
736 mg/ L	1 hour	55°C	40 – 80 %
759 mg /L	4.5 hours	38°C	40 – 80 %
759 mg /L	1 hour	55°C	40 – 80 %
736 mg/ L	1 hour	54°C	>35%
736 mg/ L	4.5 hours	38°C	>35%
736 mg/ L	1 hour	55°C	>35%
736 mg/ L	3 hours	37°C	>35%
759 mg /L	1 hour	55°C	>35%
759 mg /L	3 hours	37°C	>35%

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Premarket Notification (510(k)) Summary

Sponsor Information:

3M Health Care
3M Center, Bldg. 275-5W-06
St. Paul, MN 55144-1000

Contact Person: Matt S. Mortensen, Ph.D., RAC
Regulatory Affairs
Phone Number: (651) 737-2670
FAX Number: (651) 737-5320

Date of Summary: June 15, 2015

Device Name and Classification:

Common or Usual Name: EO Process Indicator Tape

Proprietary Name: 3M Comply™ 1224 Indicator Tape for Ethylene Oxide (EO) Sterilization

Classification Name: Indicator, physical/chemical sterilization process (21 CFR § 880.2800)

Device Classification: Class II

Product Code: JOJ

Predicate Devices:

- Indox Ethylene Oxide Indicator Tape – pre-amendment

Description of Device:

The 3M Comply™ 1224 Indicator Tape for Ethylene Oxide (EO) Sterilization is a green, pressure sensitive adhesive tape with yellow stripes that can be used to secure packages for EO sterilization. Post-sterilization the yellow stripes turn to red-maroon.

Nonclinical Comparison to the Predicate Device

The 3M Comply™ 1224 Indicator Tape for Ethylene Oxide (EO) Sterilization is similar in design to the previous generation of this product (the predicate) which was sold under the tradename Indox Ethylene Oxide Indicator Tape. In 2012 this previous version was determined by the Agency to meet the definition of a pre-amendment device. The product has been reformulated to lessen the environmental impact of solvents used in the manufacturing process. The new tape has the same intended use as the predicate.

Summary of Clinical Testing

No clinical data was included in this premarket application submission.

Indications for Use

The tape is designed to secure packs wrapped with untreated woven (i.e., reusable 100% cotton and cotton/poly blends) and disposable non-woven, paper, paper/plastic, and spunbond polyolefin/plastic wraps.

United States
Use the EO indicator tape to demonstrate that packs have been exposed to one of the EO sterilization processes in the table below and to distinguish between processed and unprocessed packs.

EO Gas Concentration	Exposure Time	Temperature	Relative Humidity %
736 mg/ L	4.5 hours	38°C	40 – 80 %
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736 mg/ L	3 hours	37°C	>35%
759 mg /L	1 hour	55°C	>35%
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Comparison to Predicate Devices

Feature	Submission Device: 3M Comply 1224 Indicator Tape for Ethylene Oxide (EO) Sterilization	Predicate Device (Pre-

<table>
<tr><td></td><td></td><td>amendment): Indox Ethylene Oxide Indicator Tape</td></tr>
<tr><td>Indications for use</td><td>The tape is designed to secure packs wrapped with untreated woven (i.e., reusable 100% cotton and cotton/poly blends) and disposable non-woven, paper, paper/plastic, and spunbond polyolefin/plastic wraps.

<u>United States</u>
Use the EO indicator tape to demonstrate that packs have been exposed to one of the EO sterilization processes in the table below and to distinguish between processed and unprocessed packs.
<table>
<tr><th>EO Gas Concentration</th><th>Exposure Time</th><th>Temperature</th><th>Relative Humidity %</th></tr>
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<tr><td>759 mg /L</td><td>3 hours</td><td>37°</td><td>>35%</td></tr>
</table></td><td>Use the EO indicator tape to demonstrate that packs have been exposed to the sterilization process and to distinguish between processed and unprocessed packs. The tape is designed to secure packs wrapped with treated and untreated woven, with treated and untreated non-woven, paper, paper/plastic, and Tyvek®/plastic wraps.</td></tr>
<tr><td>Indicator Agent</td><td>Phenol red</td><td>1,8-dihydroxyanthroquinone</td></tr>
<tr><td>Minimum exposure to critical parameters for color change</td><td>Designed to meet ISO 11140-1 Class 1 EO process indicator requirements</td><td>Identical</td></tr>
<tr><td>Recommended storage conditions</td><td>Best stored at normal room temperature conditions, 15-30°C (59-86°F) and <50% relative humidity. Store away from direct sunlight. Do not store near strong alkaline or acidic products such</td><td>Identical</td></tr>
</table>

	as cleaning/disinfecting agents. Store away from all chemical sterilants (e.g., hydrogen peroxide).	
Stability of the endpoint reaction	6 months	Identical
Shelf life	Will be based on results of completed testing at time of marketing.	18 months

Effectiveness

The effectiveness of the 3M Comply™ 1224 Indicator Tape for Ethylene Oxide (EO) Sterilization is demonstrated by the application of testing described in the Recognized Consensus Standard:

ISO 11140-1:2005/R2010; Sterilization of Health Care Products – Chemical Indicators – Part 1: General Requirements,

Color Change in Resistometer – Samples from 3 different lots were verified to meet the requirements for detectable color change post-exposure to ISO conditions in a resistometer.

Color Change in Health Care Facility Cycle – Samples from 3 different lots were verified to meet the requirements for detectable color change post-exposure in an FDA cleared 3M Steri-Vac 5XL sterilizer cycle.

End-point Color Stability – Samples from 3 different lots were verified to be stable to storage under typical office lighting conditions up to 6 months post-exposure in an FDA cleared 3M Steri-Vac 5XL sterilizer cycle.

Conclusion

The 3M Comply™ 1224 Indicator Tape for Ethylene Oxide (EO) Sterilization meets the performance standards of ISO 11140-1 and are substantially equivalent to the predicate device in terms of their intended use, physical properties and technological characteristics. The non-clinical testing demonstrates that the 3M Comply™ 1224 Indicator Tape for Ethylene Oxide (EO) Sterilization is as safe, as effective, and performs as well as the predicate device, Indox Ethylene Oxide Indicator Tape.